



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Ultane™
Docket No. 95E-0302

NOV 30 1995

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,250,334, filed by Baxter International, Inc., under 35 U.S.C. § 156 *et seq.* We have reviewed the dates contained in the application and have determined the regulatory review period for Ultane™, the human drug product claimed by the patent.

The total length of the regulatory review period for Ultane™ is 3,418 days. Of this time, 3,086 days occurred during the testing phase and 332 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(j) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 29, 1986.

The applicant claims January 10, 1986, as the date the Investigational New Drug (IND) became effective. However, FDA records indicate that the correct IND effective date was January 29, 1985, which was 30 days after agency receipt of IND 27,645 on December 30, 1985.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: July 11, 1994.

The applicant claims July 8, 1994, as the date the New Drug Application (NDA) for Ultane™ (NDA 20-478) was initially submitted. However, FDA records indicate that the applicant submitted NDA 20-478 on July 8, 1994, and the agency received the NDA on July 11, 1994, which is considered to be the NDA initially submitted date.

3. The date the application was approved: June 7, 1995.

FDA has verified the applicant's claim that NDA 20-478 was approved on June 7, 1995.

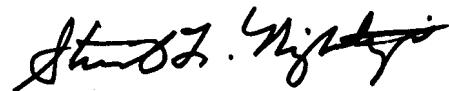
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Ultane™ - Page 2

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Henry D. Coleman
Coleman & Sudol
261 Madison Avenue
New York, NY 10016